MAR 1 6 2004

Exhibit #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K033933

1. **Submitter's Identification:**

   Preswede AB
   Flojelbergsgatan 8A
   431 35 Molndal, Sweden

   Date Summary Prepared: December 18, 2003

   Contact: Mr. John Wilhelmsson, President

2. **Name of the Device:**

   Powerlite 600® EX System.

3. **Predicate Device Information:**

   K# 030423, Powerlite600® EP System, Preswede AB, Sweden
   K#030527, Vasculight, Model SR – Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems, Lumenis, Inc.

4. **Device Description:**

   The Powerlite 600® EX System delivers pulsed light at a wavelength beginning at a wavelength of 515nm. The device consists of three interconnected sections: a light system console (including software and control electronics), a control and display panel; and one or more attached hand-piece(s).

5. **Intended Use:**

   An intense pulsed light, the Powerlite 600® EX System is indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology as follows:

   - The treatment of tattoos;
   - The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);

- The treatment of cutaneous lesions including warts, scars and striae;
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema or rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction in skin types I-V.

6. **Comparison to Predicate Devices:**

The Powerlite 600® EX System and the Vasculight/Powerlite 600® EP devices are very similar or identical in terms of the device structure and its technology. Both systems are electro-optical medical devices designed for effective photothermal treatment.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Electrical and EMC testing per IEC 60601-1 and IEC 60601-1-2 requirements

8. **Discussion of Clinical Tests Performed:**

Non-Applicable

9. **Conclusions:**

The Powerlite 600® EX System has the same intended use and similar characteristics as the Lumenis family of Intense Pulsed Light (IPL), Vasculight, Model SR and the Powerlite 600® EP System. Moreover, documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Powerlite 600® EX System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2004

Preswede AB
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K033933
Trade/Device Name: Powerlite 600® EX System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 18, 2003
Received: December 19, 2004

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K033933

Device Name: Powerlite 600® EX System

Indications For Use:

An intense pulsed light, the Powerlite 600® EX System is indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology as follows:

- The treatment of tattoos;
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
- The treatment of cutaneous lesions including warts, scars and striae;
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema or rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction in skin types I-V.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Prescription Use ✓ K033933 Over-The Counter Use_____
(Per 21 CFR 801.109) 510(k) Number_____ OR_____ (Optional Format 1-2-96)